

QUANTITY: 2 devices at Clearwater, Fla., and 5 devices at Tampa, Fla.

SHIPPED: Between the latter part of 1957 and January 1959, from Los Angeles and Hollywood, Calif., by Dimco Kitchen Equipment, and Allure, Inc.

LABEL IN PART: "Allure Mfd. by Allure Inc. Hollywood, Calif."

ACCOMPANYING LABELING: Claim (one device) for patent application and (one device) circulars entitled "Allure Salon Bust Developing and Firming."

RESULTS OF INVESTIGATION: The article consisted of rubber-ringed plastic cups of various sizes which had small openings for connection to rubber hoses attached to an air compressor or electrically operated pump. Attached to the compressor was a pressure regulator, a vacuum gauge, and a valve to regulate the amount of vacuum produced in each of the two breast cups while in use. The plastic cups were pressed over the breasts against the chest and the rubber-ringed edge formed an airtight seal. The air compressor was then operated to form a vacuum inside the cups to exercise the breasts by contraction and relaxation. The air compressor and accessory equipment were contained in a metal cabinet 36" x 22" x 18".

LIBELED: 8-31-59, S. Dist. Fla.

CHARGE: 502(a)—when shipped and while held for sale, the labeling, namely, the circular entitled "Allure Salon Bust Developing and Firming," which accompanied one device at Tampa, Fla., contained false and misleading representations that the device was a safe, adequate, and effective treatment for increasing the size of the female breast; for developing the breasts without surgery, hormones, creams, or exercise; that it was capable of bringing about complete bust correction and a beautiful bust line; that it would restore youth, beauty, and glamour; and that use of the device was healthful; and the labeling, namely, the claim for patent application, which accompanied another device at Tampa, Fla., contained false and misleading representations that the article was an adequate and effective treatment for development of the human female breast; 502(f)(1)—the labeling of the article (all lots) failed to bear adequate directions for use for the purposes for which it was intended; and 502(j)—the article (all lots) was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling.

DISPOSITION: 12-7-59. Default—delivered to the Food and Drug Administration.

## NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

### DRUGS FOR HUMAN USE

6303. Supplement to notice of judgment on drugs and devices, No. 6003. Vitamin B<sub>12</sub> injection. F.D.C. No. 40930, S. No. 67-040 M.

The notice of judgment in the above-identified case is incomplete in that it fails to report the order of dismissal with respect to the adulteration charge under Section 501(b) and the basis upon which the claimant of the article, Maizel Laboratories, Inc., consented to the entry of a decree of condemnation. In order that the notice of judgment may reflect these facts, the provisions of the decree of condemnation are set forth below in their entirety:

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF  
MARYLAND

UNITED STATES OF AMERICA

v.

144 vials, more or less, of an article of drug  
labeled in part:

Civil No. 10122

"Intramuscular 10 c.c. Intravenous VITAMIN  
B<sub>12</sub> INJECTION Cyanocobalamin U.S.P. 1000  
mcg. Each c.c. contains a sterile solution of 1000  
micrograms Vitamin B<sub>12</sub> U.S.P. (Cyanocobalamin)  
in normal saline with 2% Benzyl Alcohol as  
preservative. \* \* \* 28590 \* \* \*"

CONSENT DECREE OF  
CONDEMNATION

"On November 1, 1957, a Libel of Information against the above-described article was filed in this Court on behalf of the United States of America by the United States Attorney and Assistant United States Attorney for this District. The Libel alleges that the article proceeded against is a drug which is violative of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 334 in that it was adulterated when introduced into and while in interstate commerce within the meaning of 21 U.S.C. 351(b) and that it is a New Drug which may not be introduced or delivered for introduction into interstate commerce under the provisions of 21 U.S.C. 355(a) since an application filed pursuant to 21 U.S.C. 355(b) is not effective with respect to such drug. Pursuant to Monition issued by this Court, the United States Marshal for this District seized said article of drug on November 5, 1957. Thereafter, Maizel Laboratories, Inc., of Chicago, Illinois, appeared as claimant and filed answer to the Libel.

"Claimant, through its attorney, represents to the Court that the intrinsic value of the drug under seizure in this case is negligible, and further that the standard set forth in the United States Pharmacopoeia for this drug has been clarified to include a specific test for solids, which test was not part of the United States Pharmacopoeia monograph at the time of shipment, and without admitting any of the issues of law and fact involved, claimant consents that a Decree of Condemnation and Destruction may be entered in this case pursuant to 21 U.S.C. 334, for violation of 21 U.S.C. 355.

"The Court being fully advised in the premises, and in view of claimant's consent to condemnation and destruction of the seized drug for violation of 21 U.S.C. 355, it being unnecessary to adjudicate the allegation of violation under 21 U.S.C. 351(b), and the parties having therefore agreed to the dismissal of the allegation of violation under 21 U.S.C. 351(b) it is,

"ORDERED, ADJUDGED, AND DECREED that the article of drug under seizure is violative of 21 U.S.C. 355, in that it is a New Drug which may not be introduced or delivered for introduction into interstate commerce under the provisions of 21 U.S.C. 355(a) since an application filed pursuant to 21 U.S.C. 355(b) is not effective with respect to such drug, and it is hereby condemned pursuant to 21 U.S.C. 334(a) and that said article shall be destroyed by the United States Marshal for this District pursuant to 21 U.S.C. 334(d); and it is further

"ORDERED, ADJUDGED, AND DECREED, that the allegation of violation under 21 U.S.C. 351(b) be, and hereby is dismissed; and it is further

"ORDERED, ADJUDGED, AND DECREED, pursuant to 21 U.S.C. 334(e), that the libelant shall recover from the claimant all court costs and fees and storage and other proper expenses to be taxed after destruction of said article of drug."

Dated this 10th day of August 1959.

W. CALVIN CHESTNUT,

United States District Judge.